

Rule to Strengthen Transparency in Pivotal Science Underlying Final Significant Regulatory Actions and Influential Scientific Information

ISSUE SUMMARY:

On April 30, 2018, EPA published in the Federal Register a proposed rule to *Strengthen Transparency in Regulatory Science*. The public comment period originally closed on May 30, 2018, but after requests from the public and House and Senate Democrats, the comment period was extended to August 16, 2018. On July 17, 2018, an EPA public hearing was held in Washington, D.C.

On March 18, 2020, a supplemental notice of proposed rulemaking (SNPRM) was published in the Federal Register. The 30-day public comment period was extended for an additional 30 days and closed on May 18, 2020. The SNPRM included clarifications, modifications, and additions to certain provisions in the 2018 proposed rule, including expanding the scope to include influential scientific information.

The rulemaking is intended to apply prospectively to final significant regulatory actions and influential scientific information and would require that data and models underlying pivotal science used to support these significant actions, regardless of who generated or funded them, be made available for independent validation. The rulemaking provides criteria for the Administrator to consider when granting case-by-case exemptions to the requirements of the rule:

- 1) technological or other barriers render sharing of the data or models infeasible;
- 2) the development of the data or model was completed or updated before the effective date of the rule; or
- 3) making the data and models publicly available would conflict with laws and regulations governing privacy, confidentiality, confidential business information, or national and homeland security.

This is a rule of internal Agency procedure. No requirements are imposed on third parties. This rule requires consideration of data and model availability, specifically that EPA give greater consideration to those studies where the underlying data and models are available in a manner sufficient for independent validation. However, EPA is not responsible for ensuring the availability of the data and models. Data are considered available if they are available to the general public or through a restricted access data repository or secure data enclave, in the case of protected data that cannot be deidentified.

UPCOMING MILESTONES:

- **Late 2020** – EPA expects to publish the final rule.

BACKGROUND:

EPA received feedback from the Science Advisory Board (SAB) in two letters: On September 30, 2019, SAB provided feedback on personally identifiable information and confidential business information and in an April 24, 2020, letter

SAB provided feedback on the overall proposal and supplemental proposal. EPA is considering those comments in development of the final rule.

KEY EXTERNAL STAKEHOLDERS:

☒ Congress ☒ Industry ☒ States ☒ Tribes ☒ Media ☒ Other Federal Agency
☒ NGO ☐ Local Government ☐ Other (Local unions)

Congress is very interested in this rule and Members have sent many letters to EPA about it. Congressmembers Paul Tonko (D-NY-20), Suzanne Bonamici (D-OR-01), and Dan Lipinski (D-IL-03) have been very vocal about their opposition to the proposed rule. All three provided comments during the July 2018 public hearing. Eighty-five House members signed a March 23, 2020, letter asking for the rule to be withdrawn.

Many public health and science organizations have made statements about the rule and provided comments. During the 2018 public comment period EPA received almost 600,000 public comments. Approximately 9,200 were unique comments. Most commenters generally supported greater transparency but the majority (>75%) oppose some aspect of the proposed approach and made comments to improve the proposal.

During the 2020 public comment period on the SNPRM, EPA received almost 400,000 public comments, of which almost 3,800 are unique.

MOVING FORWARD:

- Late 2020 – EPA expects to publish the final rule.
- EPA has stood up an Agency workgroup to develop implementation guidance for this rule.

LEAD OFFICE/REGION: ORD

OTHER KEY OFFICES/REGIONS: OGC, PROGRAM OFFICES